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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/579,933 05/26/00 GOEDDEL

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EXAMINER

SCHEINER, L

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/10/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/579,933

Applicant(s)

Examiner

Group Art Unit

1648

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/21/00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 35-37 & 39-42 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 35-37 & 39-42 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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Claims 35-37 and 39-42 are pending in this application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-37 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). Claims 35-37 and 39-42 are drawn toward methods of treating patients having (or at risk of having) Epstein-Barr associated virus tumors with a therapeutically acceptable amount of an I-TRAF, as well as a pharmaceutical formulation comprising a therapeutically effective amount of an I-TRAF polypeptide and a pharmaceutically acceptable carrier. The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable one skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano*,

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25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell*, 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). *In re Deuel*, 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995).

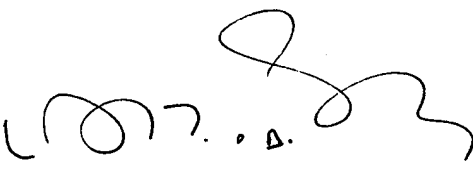
Applicants' disclosure fails to provide adequate written support for the invention as claimed. That is, the claims are drawn to methods of treating patients having (or at risk of having) Epstein-Barr associated virus tumors with a therapeutically acceptable amount of an I-TRAF. Essentially, based on the instant disclosure, the skilled artisan is being asked to predict the functionality of a protein based on its sequence. The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. The specification asserts that the I-TRAF can be used in Epstein-Barr associated tumor therapy techniques. However, this is a highly unpredictable technology and the specification fails to establish a clear correlation between the instant in vitro system and in vivo results. There is no guidance in the specification regarding determining the therapeutically effective amount of I-TRAF for human administration. That is, there is no teaching or guidance indicating what dosages are required and by what routes the protein can be effectively administered or otherwise used in a practical manner for tumor treatment in patients. The success of the proteins as pharmaceutical agents is dependent on adequate concentrations of drug reaching the target site, for example. There are many pharmacokinetic properties of peptide/protein drugs such as half-life, deactivation by the liver, binding to plasma proteins such as albumin, renal clearance, toxic side effects, and so forth, that cannot be ascertained from the specification. For these reasons, using instant I-TRAF in pharmaceutical compositions is not enabled by the disclosure and the specification fails to provide an adequate written description of the claimed invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

  
Laurie Scheiner/LAS  
September 29, 2001

  
LAURIE SCHEINER  
PRIMARY EXAMINER